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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/719,320	11/21/2003	Kenneth James Kozak	100736/0504851	3081
26874	7590	07/07/2005	EXAMINER	
FROST BROWN TODD, LLC 2200 PNC CENTER 201 E. FIFTH STREET CINCINNATI, OH 45202			PORTNER, VIRGINIA ALLEN	
			ART UNIT	PAPER NUMBER
			1645	

DATE MAILED: 07/07/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/719,320	KOZAK, KENNETH JAMES	
	<b>Examiner</b>	<b>Art Unit</b>	
	Ginny Portner	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 20 April 2005.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-16 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)             | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

### **DETAILED ACTION**

Claims 1-16 are pending. Amended claim 1 and dependent claims 2-10 recite a new combination of claim limitations.

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

#### ***Claim Objections***

1. (Objections withdrawn) Claims 1, 7 objected to because of the following informalities have been obviated through amendment of claim 1 to only recite letter designators and claim 7 to depend from claim 5, and not directly from claim 1; claim 7 is now further limiting of the claims from which it depends.

#### ***Claim Rejections - 35 USC § 102***

2. (Rejection Withdrawn, in part) Claims 1- 10 rejected under 35 U.S.C. 102(e, effective filing date October 29, 1998) as being anticipated by Reiter et al (US 2004/ 0023316 A1) as evidenced by US Pat. 6,793,958 is herein withdrawn in light of the amendment of the claims to recite a new phrase “wherein such antigen specific antibodies bind to the H.pylori antigen and do not react with different species and strains of Helicobacter or Campylobacter”, and new grounds of rejection set forth below.

#### ***Response to Arguments***

3. Applicant's arguments filed April 20, 2005 have been fully considered but they are not persuasive.
4. (Maintained in part) The rejection of claims 11-16 under 35 U.S.C. 102(e, effective filing date October 29, 1998) as being anticipated by Reiter et al (US 2004/ 0023316 A1) as

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evidenced by US Pat. 6,793,958, is traversed on the grounds that the present assay “does NOT use genus directed antibodies on both sides of the assay but only uses such genus directed antibodies on ONE side of the assay.

5. It is the position of the examiner that claims 11-16, do not depend from amended claim 1, and therefore do not recite the combination of claim limitations used to traverse the instantly claimed invention “wherein such antigen specific antibodies bind to the H.pylori antigen and do not react with different species and strains of Helicobacter or Campylobacter”.

6. The antibodies of the invention set forth in claims 11-16 are a genus specific monoclonal antibody combined with either an H.pylori antigen specific polyclonal antibody or a combination of H.pylori specific monoclonal antibodies. It is the position of the examiner that the term “specific” recited in the claims defines a continuum of specificities, and not an absolute binding specificity for a single bacterial pathogen, but defines specific binding to its antigen without non-specific binding. All antibodies specifically bind to the antigen to which they were raised, but may also bind to the same antigenic epitope from other sources.

7. Applicant’s instant Specification teaches the utilization of ATCC 43504 (whole cell antigen) in the production of Helicobacter pylori specific polyclonal antibodies. Upon consideration of antigen analysis of H.pylori strains, including strain ATCC 43504, the examiner found Meyer et al (PG-Pub 2003/01800330) to teach the presence of a number of antigens that will induce antibodies that will immunoreact with more than one strain or species of bacteria (see Meyer et al (PG-Pub 2003/01800330, paragraph [0086; 0127; 0137; 0139 and 0273].

Applicant’s traversal is not commensurate in scope with the instantly claimed invention therefore the prior art rejection is maintained for reasons of record and responses set forth above.

***New Claim Limitations/New Grounds of Rejection***

***Claim Rejections - 35 USC § 112***

8. Claims 1-10 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

9. Claims 1-10 have been amended to recite the phrase ““wherein such antigen specific antibodies bind to the H.pylori antigen and do not react with different species and strains of Helicobacter or Campylobacter””; this phrase does not evidence original descriptive support in the instant specification.

10. While the Specification does provide support for the term “specific”, this term includes a continuum of specificity (low, moderate or high specificity), and is not limited to the absolute lack of reactivity with other strains and species now claimed. All of the claims recite a combination of claim limitations for which the instant Specification does not provide original descriptive support and therefore recite New Matter.

***Conclusion***

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO**

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MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ginny Portner whose telephone number is (571) 272-0862. The examiner can normally be reached on 7:30-5:00 M-F, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (571) 272-0864.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Vgp  
July 5, 2005



MARK NAVARRO  
PRIMARY EXAMINER